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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/813,747

03/29/2004

Stan Gronthos

A20-033CIP

7277

7590

12/15/2006

Henry D. Coleman
714 Colorado Avenue
Bridgeport, CT 06605-1601

EXAMINER

BELYAVSKYI, MICHAEL A

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 12/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--|--|--|
| Office Action Summary | Application No. 10/813,747 | Applicant(s) GRONTHOS ET AL. | |
| | Examiner Michail A. Belyavskyi | Art Unit 1644 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-78 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-78 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment, filed 03/29/04 is acknowledged.
2. Claims 1-78 are pending.
3. In view of Applicant's Amendment filed on 03/29/04 that was not timely entered, the previous Restriction Requirement mailed on 07/10/06 is hereby vacated.

The new Restriction Requirement is set forth below. Examiner apologized for any inconveniences.

Restriction Requirement

4. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
 - I. Claims 1-4, 9-12, 14-17, 19, 24-31, 34-39 drawn to an isolated mammalian cells, wherein said cells co-expresses MUC18/CD146, classified in Class 435 , subclass 372.
 - II. Claims 1-3, 5, 9-12, 14-17, 19, 24-31, 34-39 drawn to an isolated mammalian cells wherein said cells co-expresses alpha smooth muscle actin, classified in Class 435 , subclass 372.
 - III. Claims 1-3, 6, 9-12, 14-17, 19, 24-31, 34-39 drawn to an isolated mammalian cells wherein said cells co-expresses STRO-1^{bri}, classified in Class 435 , subclass 372.
 - IV. Claims 1-3, 7, 9-11, 13-17, 19, 24-31, 34-39 drawn to an isolated mammalian cells wherein said cells co-expresses a marker recited in claims 7 or 13, classified in Class 435 , subclass 372.
 - V. Claims 1-3, 8, 9-10, 15-17, 19-31, 34-39 drawn to an isolated mammalian cells wherein said cells co-expresses STRO-1^{bri}, MUC18/CD146 and alpha smooth muscle actin and MPC capable of forming clonogenic colony classified in Class 435 , subclass 372.

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- VI. Claims 18 and 33 drawn to a differentiated progeny cells, obtained from the isolated MPC that is positive for the surface marker 3G5, classified in Class 435 , subclass 377.
- VII. Claims 18 and 33 drawn to a differentiated progeny cells, obtained from the isolated MPC that is positive for the surface marker Stro-1, classified in Class 435 , subclass 377.
- VIII. Claims 20-23, 70-78 drawn to an unexpanded population of cells enriched for mesenchymal precursor cells, wherein said cells co-expresses MUC18/CD146 and alpha-smooth muscle actin , classified in Class 435 , subclass 372.
- IX. Claims 40 - ,42,45, 46 -56, 57, 60-65 drawn to a method of enriching for mesenchymal precursor cells based on the presence of the marker 3G5, classified in Class 435 , subclass 375.
- X. Claims 40, 41, 43 ,45, 46 -56, 58, 60-65 drawn to a method of enriching for mesenchymal precursor cells based on the presence of the marker MUC18/CD146, classified in Class 435 , subclass 375.
- XI. Claims 40, 41, 44 ,45, 46-56, 59, 60-65 drawn to a method of enriching for mesenchymal precursor cells based on the presence of the marker Stro-1^{bri}, classified in Class 435 , subclass 375.
- XII. Claims 66 and 67 drawn to a method of expending MPC , classified in Class 435 , subclass 375.

5. Groups I-VIII are different products. These inventions are differ with respect to their structures and physicochemical properties, which require non-coextensive searches; therefore each product is patentably distinct.

6. Groups IX – XII are different methods. These inventions are different with respect to ingredients, method steps, and endpoints which require non-coextensive searches ; therefore, each method is patentably distinct.

7. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods

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of use comprising distinct method steps. Moreover, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

8. The examiner has required restriction between product and process claims. If applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

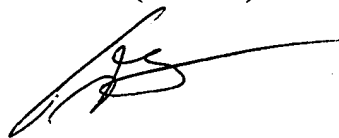
10. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is 571/ 272-0840. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/ 272-0841.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



MICHAIL BELYAVSKYI, PH.D.
PATENT EXAMINER

12/08/06